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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,669	10/31/2001	Jerome T. Hartlaub	11738.00046	5026
27581	7590	06/13/2007	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			NAJARIAN, LENA	
		ART UNIT	PAPER NUMBER	
		3626		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/002,669	HARTLAUB, JEROME T.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 April 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-48 is/are pending in the application.
 4a) Of the above claim(s) 1-11 and 27-38 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 12-26 and 39-48 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Request for Continued Examination (RCE) filed 4/17/07. Claims 12 and 21 have been amended. Claims 39-48 are newly added. Claims 12-26 and 39-48 have been examined.

Specification

2. The amendment filed 4/17/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The newly added recitation of "automatically, and without scheduling input contemporaneously provided by the patient" within claims 12 and 21 appears to constitute new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Independent claims 12 and 21 recite limitations that are new matter, as discussed above, and are therefore rejected. The specification does not describe a negative limitation that eliminates needing a patient's input. For example, the portion of the specification pointed to by Applicant for support of the added material, states receiving preferences of the patient and that these preferences are manually provided to the appointment scheduling module (paragraph 53 of Specification).

Drawings

5. The objection to the drawings is hereby withdrawn due to the amendment filed 4/17/07.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

NOTE: The following rejections are provided, upon the assumption that Applicant successfully traverses the new matter objections and rejections given above.

7. Claims 12-15, 17-26, 39-41, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Garcia (6,088,429).

(A) Referring to claim 12, Lebel discloses an implantable drug delivery device for delivering at least one drug to a patient comprising in combination (abstract of Lebel):

(a) at least one reservoir each containing at least one drug (para. 60 of Lebel);

(b) a drug scheduling module for determining whether the drug should be replenished (para. 179 of Lebel); and

(d) a telemetry module providing bi-directional communications with an external device (Fig. 3 of Lebel),

wherein the drug scheduling module receives data about the implantable drug delivery device, wherein the data is drug usage information (para. 179 and para. 180 of Lebel).

Lebel does not disclose an appointment scheduling module for automatically, and without scheduling input contemporaneously provided by the patient, scheduling an appointment to replenish the drug in the device and allowing the appointment scheduling module to schedule the appointment.

Garcia discloses an appointment scheduling module for automatically, and without scheduling input contemporaneously provided by the patient, scheduling an appointment to replenish the drug and allowing the appointment scheduling module to schedule the appointment (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Garcia within Lebel. The motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58–65 of Garcia).

Insofar as the claim recites “selected from the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 13, Lebel discloses wherein the module contacts via the external device at least one entity, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient (para. 134 of Lebel).

Lebel does not expressly disclose an appointment scheduling module.

Garcia discloses an appointment scheduling module (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58–65 of Garcia).

(C) Referring to claim 14, Lebel discloses the drug scheduling module further receives data (para. 320 of Lebel).

(D) Referring to claim 15, Lebel discloses wherein the drug management instructions is deliver drug to a specified location (para. 204 of Lebel).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

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(E) Referring to claim 17, Lebel discloses wherein the drug scheduling module includes a drug management algorithm to forecast when a next refill of pump reservoir is required (para. 179, para. 207, and para. 318 of Lebel).

(F) Referring to claim 18, Lebel does not disclose wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

Garcia discloses wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is the patient (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58-65 of Garcia).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(G) Referring to claims 19 and 20, Lebel discloses wherein the implantable drug delivery device is in communication with a computing device, the computing device operatively coupled to the entity (see Fig. 3 of Lebel).

Lebel does not disclose wherein the computing network is the Internet.

Garcia discloses wherein the computing network is an Internet (col. 9, lines 58-59 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide easier access that is available world wide (col. 9, lines 58-59 of Garcia).

(H) Referring to claim 21, Lebel discloses an implantable drug delivery device, comprising (para. 204 and Fig. 3 of Lebel):

- (a) a housing (para. 204 and Fig. 3 of Lebel);
- (b) a drug reservoir carried in the housing configured to contain a therapeutic substance (para. 204 and Fig. 3 of Lebel);
- (c) a flow control coupled to the drug reservoir for controlling the flow of the therapeutic substance from the drug reservoir through an infusion port (para. 204 and Fig. 3 of Lebel);
- (d) electronics coupled to the flow control and a power source (para. 204 and Fig. 3 of Lebel);
- (e) a telemetry module coupled to the electronics (para. 204 and Fig. 3 of Lebel);
- (f) memory coupled to the electronics, the memory containing pump refill criteria and other refill criteria (para. 204, para. 179, para. 186, and Fig. 3 of Lebel);
- (g) a monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable (para. 204, para. 179, and para. 186 of Lebel); and,
- (h) a refill module coupled to the memory and the electronic, the refill module configured to calculate at least one relationship among the pump refill criteria, other refill

criteria, and monitored pump variables, the refill module configured to decide whether a pump refill activity should be reported, and the refill module configured to activate the telemetry module to report a refill activity, wherein the module is adapted to contact via the telemetry module a physician for the scheduling activity (para. 204, para. 179, para. 186, Fig. 3, para. 132, and para. 134 of Lebel).

Lebel does not expressly disclose patient scheduling automatically, and without scheduling input contemporaneously provided by the patient.

Garcia discloses patient scheduling automatically, and without scheduling input contemporaneously provided by the patient (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58-65 of Garcia).

Insofar as the claim recites "selected from the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(I) Referring to claim 22, Lebel discloses wherein the refill module determines whether an appointment is necessary to perform a pump refill (para. 179 and para. 186 of Lebel).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(J) Referring to claim 23, Lebel discloses wherein the refill module communicates via the telemetry module with an external device (Fig. 3 of Lebel).

(K) Referring to claim 24, Lebel discloses contacting the patient via the telemetry module (para. 134 and Fig. 3 of Lebel).

Lebel does not disclose wherein the scheduling module contacts the patient for the scheduling activity.

Garcia discloses wherein the scheduling module contacts the patient for the scheduling activity (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58-65 of Garcia).

(L) Claims 25 and 26 repeat the same limitations of claims 19 and 20, and are therefore rejected for the same reasons given for those claims.

(M) Referring to claim 39, Lebel does not disclose wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled to initiate the automatic scheduling of an appointment.

Garcia discloses wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled to initiate the automatic scheduling of an appointment (col. 6, lines 17-28 and col. 14, lines 35-55 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide a more convenient system for the participants.

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(N) Referring to claim 40, Lebel does not disclose wherein the scheduling management algorithm receives predetermined scheduling preferences upon being enabled to initiate the automatic scheduling of an appointment.

Garcia discloses wherein the scheduling management algorithm receives predetermined scheduling preferences upon being enabled to initiate the automatic scheduling of an appointment (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been for the system to schedule the appointment at a time requested by the patient (col. 6, lines 17-28 of Garcia).

(O) Referring to claim 41, Lebel does not disclose wherein the predetermined preferences are date, time and place preferences of the patient and a caregiver.

Garcia discloses wherein the predetermined preference is a time preference of the patient (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been for the system to schedule the appointment at a time requested by the patient (col. 6, lines 17-28 of Garcia).

Garcia does not expressly disclose date and place preferences. However, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to include the aforementioned features with the motivation of informing the participants of pertinent details needed in order to attend an appointment.

Insofar as the claims recites "selected from the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(P) Claims 44-46 repeat the same limitations as claims 39-41, and are therefore rejected for the same reasons given above.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Garcia (6,088,429), and further in view of Akers et al. (6,112,182).

(A) Referring to claim 16, Lebel and Garcia do not disclose wherein the drug scheduling module receives drug management data selected from the group consisting of name of drug manufacturer, date drug was manufactured, and name of pharmacy carrying the drug.

Akers discloses wherein the drug scheduling module receives drug management data such as name of drug manufacturer (col. 5, lines 18-21 of Akers).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Akers within Lebel and Garcia. The motivation for doing so would have been for a comprehensive drug record (col. 5, lines 18-21 of Akers).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

9. Claims 42-43 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Garcia (6,088,429), and further in view of Cummings, Jr. et al. (US 6,345,260 B1).

(A) Referring to claim 42, Lebel and Garcia do not disclose wherein the appointment scheduling module records whether all entities being scheduled have acknowledged acceptance of the scheduled appointment.

Cummings discloses wherein the appointment scheduling module records whether all entities being scheduled have acknowledged acceptance of the scheduled appointment (col. 8, lines 38-57 of Cummings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cummings within Lebel and Garcia. The motivation for doing so would have been to provide a tentative booking confirmation of the appointment (col. 8, lines 38-57 of Cummings).

(B) Referring to claim 43, Lebel and Garcia do not disclose wherein the appointment scheduling module searches for another appointment time in the event that not all entities being scheduled have acknowledged acceptance of the scheduled appointment.

Cumming discloses wherein the appointment scheduling module searches for another appointment time in the event that not all entities being scheduled have acknowledged acceptance of the scheduled appointment (col. 6, lines 16-18 of Cummings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cummings within Lebel and

Garcia. The motivation for doing so would have been to find other available appointment times and dates (col. 6, lines 16-18 of Cummings).

(C) Claims 47-48 repeat the same limitations as claims 42-43, and are therefore rejected for the same reasons given above.

Response to Arguments

10. Applicant's arguments filed 4/17/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 4/17/07.

(1) Applicant argues that Garcia does not disclose a module that schedules an appointment without a human having to contemporaneously interact with the medication data system.

(A) As per the first argument, the Examiner respectfully submits that Garcia teaches a patient utilizing a menu to indicate a preferred appointment time. The system can then automatically schedule an appointment for the patient (col. 6, lines 17-28 of Garcia). As such, it is readily apparent that at time of actual scheduling, there is no human interaction.

Conclusion

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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In
6-7-07

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